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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,009

09/26/2003

Laurent Schaller

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05/12/2009

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

NOTIFICATION DATE

DELIVERY MODE

05/12/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/672,009	<b>Applicant(s)</b> SCHALLER ET AL.	
	<b>Examiner</b> TUAN V. NGUYEN	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-40 is/are pending in the application.
- 4a) Of the above claim(s) 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-40 were pending in this present application. In previous Office action, claims 1-33 were examined and rejected and claims 34-40 have been withdrawn.
2. This Office action is in response to the amendment filed on 1/29/2009.

#### ***Response to Amendment***

3. According to the amendment, claim 18 has been canceled. Accordingly, claims 1-17 and 19-40 are pending in this present application and claims 1-17 and 19-33 are presented for examination.

#### ***Response to Arguments***

4. Applicant's arguments with respect to rejection of claims 1, 2, 6/1, 6/2, 7/1, 7/2, 8, 14/8, 15/8, 16/8, 17-28 and 30-33 under 35 USC 102(e) have been fully considered but they are not persuasive for the reasons set forth below.
  - a. Applicant argues that the clip 134 of Edoga is not shape memory self-closing clips is in correct. Noting that nowhere in claims 1, 2, 6/1, 6/2, 7/1, 7/2, 8, 14/8, 15/8, 16/8, 17-28 and 30-33 claimed a shape memory self-closing clip. Further, only in claim 1, line 3, recites a self-closing clip. Edoga, fails to disclose the clip 134 is made of shape memory material, however, wire segment 134 formed into clip 158 as shown in Figs 8 and

15D required no additional structure to keep the clip 158 closing, thus, the clip 158 read on the limitation of “self-closing clip”.

- b. Applicant argues that the staple guides 140 are not barbs, rather, they are disclosed as hooked staple guides is incorrect. Examiner contents that the hook of the staple guides is equivalent to the structure of a barb.
  - c. With respect to independent claims 17, 22 and 28 (currently amended by the amendment), Applicant argues that Edoga fails to disclose the clips are separate from said barbs and are movable independently of said barbs is in correct. Edoga clearly disclose that that wire segments 134, subsequently formed into clips 158 are movable independently of the guide 140. Nowhere in the specification and drawings of Edoga discloses the wire segment 134 are fixedly attached to the staple guides 140.
5. Applicant's arguments with respect to rejection of claims 1-17 and 19-33 under 35 USC 103(a) have been fully considered but they are not persuasive. Applicant argues that there is no incentive to modify Miller in the manner suggested by the Examiner and there is no reason or suggestion either in the references themselves is incorrect. Loshakove discloses (Figs. 5A-5F) an anastomosis device comprising, among other things, a plurality of puller 512 for pulling the lips of the incision of the blood vessel into a desired location relative to another lip for effecting anastomosis connection ([0006], [0095]-[0100]). Therefore, It would have been obvious to one of ordinary skill in the art to replace the pivoting arms 172 of Miller device with the

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pullers as disclosed by Loshakove in order to improve the effectiveness and safety of Miller device.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

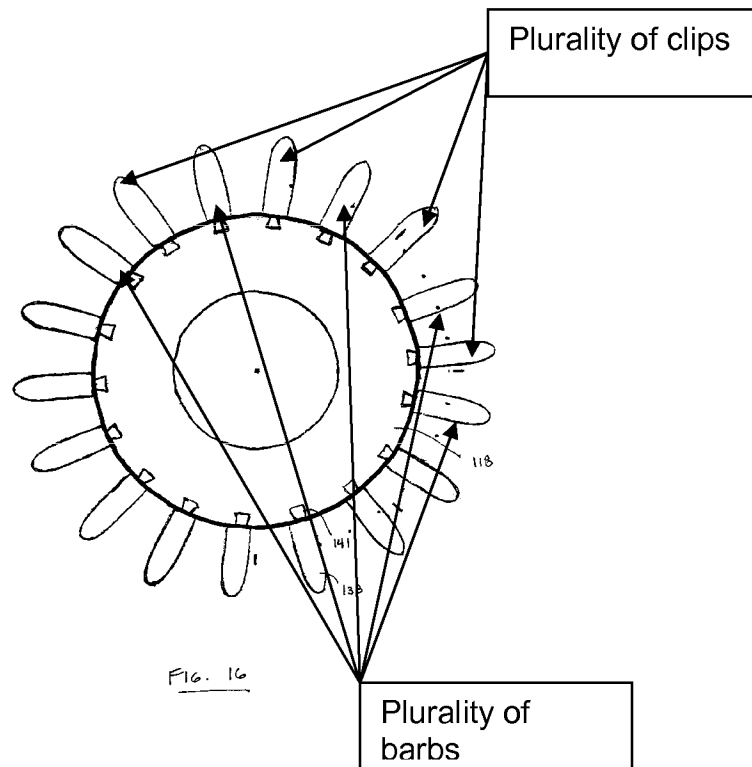
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1, 2, 6/1, 6/2, 7/1, 7/2, 8, 14/8, 15/8, 16/8, 17-28 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Edoga et al. (US 7335212).**
8. Edoga discloses (Figs. 2-7, and 16, col. 3, line 50 to col. 4, line 65 and col. 6, lines 14-40) an anastomosis device comprising: a support structure, which is the tubular structure that graft 110 is attached onto; a plurality of wire segment 134, which formed into self-closing clips 158, each clip being releasably coupled to the first plurality of members 132 and the support structure 101; a trigger 108 or a first plunger 108 movably coupled to the support structure, wherein the first plunger 108 includes plurality of pusher 138, each pusher coupled to a clip for simultaneously deployment of the clips; plurality of barbs 140 being coupled to the support structure, the barbs being separate and from the clips and each barbs slidably disposed in one second plurality of paths 141; and a second plunger 118

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movably coupled to the support structure 101 and the second plunger being coupled to the proximal end of each barb 140 for simultaneously extending the barbs between a first position where they extend from the support structure (Fig. 5) and a second position where they are retracted into the support structure (Fig. 4). Noting that the wire segments 134 are movable independently of the guide tubes 140.

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**Claim Rejections - 35 USC § 103**

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. 6,709,442) in view of Loshakove (US Patent Application Pub. No. 2004/0087985).**

12. Miller discloses (see Figs. 5A-5F and 13-34) anastomosis device 50, 170 comprising: a support structure 51, 57 or 226, 218, 220; one or plurality of self-closing clip 10, 236 slidably and disposed in tube 51 or plurality of tube 230 (or first plurality of member), wherein the clips is shape memory clip and the clips assume a shape that automatically applies to the layers of tissue an appropriate hemostatic compression which is relatively independent of tissue thickness (see col. 3, lines 54-60), each clip being releasably coupled to said support structure by

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- plunger 52, 238; a pusher, 60, 210 is connected to plunger 52, 238; and the clips can be deployed simultaneously (see col. 7, line 46 to col. 8, line 40 and col. 12, line 50 to col. 13, line 25). Miller discloses (Figs. 13-32) the device also includes a plurality of pivot arms 172 for supporting the lips of the anastomosis vessels during the deployment of the fasteners (col. 11, lines 1-43). Miller discloses the invention substantially as claimed except for the device further includes a plurality of barbs, each barb being coupled to the support structure and the barbs being separate from the clips, which are ejectable from the support structure independently of the barbs. Noting that the self-closing clip 10, 236 are movable independently of the
13. However, Loshakove discloses (Figs. 5A-5F) an anastomosis device comprising, among other things, a plurality of puller 512 for pulling the lips of the incision of the blood vessel into a desired location relative to another lip for effecting anastomosis connection ([0006], [0095]-[0100]). It would have been obvious to one of ordinary skill in the art to replace the pivoting arms 172 of Miller device with the pullers as disclosed by Loshakove in order to improve the effectiveness and safety of Miller device. Miller as modified by Loshakove discloses the self-closing clip 10, 236 are movable independently of the of the barb 108.
14. Referring to claim 13, Miller disclosed that Nitinol is a "shape memory alloy" that capable of having strain ratio of up to 8% without experiencing permanent deformation (col. 5, lines 60-65). It would have been obvious to one of ordinary skill in the art to make the puller from Nitinol so that it too would have this same advantage.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **TUAN V. NGUYEN** whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
5/7/09